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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,569	08/20/2001	Thomas Wild	9793/97	5757

23690 7590 11/06/2002

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EXAMINER	
DAVIS, DEBORAH A	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/06/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,569	WILD ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-32* is/are pending in the application.

4a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 8 is acknowledged.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claims 11-26, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by

"or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

5. The method of claim 11 lacks the necessary step of forming a binding complex with the analyte, therefore, it is unclear whether the first hapten or the second hapten or hapten-like molecule is forming said binding complex.

Step "(e)" of claim 11 recites the limitation "measuring a signal" is vague and indefinite because it is unclear as to what reagents are being measured or how the reagents interact when combined together.

6. Claims 12 and 22 recite the limitation "wherein the analyte specific component is selected from a group consisting of the analyte, an analyte analogue, and a binding partner of the analyte" is unclear because the "analyte specific component" identified in claims 11 and 22, from which the claims depend, comprises a hapten linked to an analyte specific component, so then how does the "analyte specific component" consist of "the analyte", "an analyte analogue", or a "binding partner of the analyte", what is the relationship of the hapten?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 11-15 and 17-19, 21-23, 25-26 are rejected under 35 U.S.C. 102(b) as being by Hevey et al (USP#4,228,237).

Hevey et al teaches methods for the detection and determination of ligands utilizing a biotin/avidin system. Claims 11-14 and 17-19 are anticipated by the reference in teaching several embodiments of an assay and methods that determine the presence and amount of a ligand. One embodiment teaches a competitive binding process comprising a specific binding substance for a ligand (binding partner) and the reagents consists of a biotin labeled ligand (1^{st} hapten and antibody specific for the ligand) and an enzyme labeled avidin (2^{nd} hapten) (col. 3, lines 40-45). Hevey et al teaches that when the ligand is a hapten, a specific binding substance utilized to detect the hapten is an antibody produced when the hapten, bound to an antigenic carrier is introduced into a sample (col. 4, lines 61-65). Hevey et al teaches that during the binding steps, the reagents may be incubated individually or in particular sequence, as taught in claims 11, 17-18 (col. 2, lines 58-62). The reaction is measured by the activity of the enzyme labeled avidin (col. 3, lines 64-68 & col. 4, lines 1-5). Examples of solid carriers used in this invention range from microtiter plates to nylon beads. When nylon beads are used, the appropriate antibody may be covalently coupled to the beads, as taught in claim 23 (col. 5, lines 32-41). HRP labeled avidin is pre-reacted with biotin labeled antibody, which is added to the insoluble phase after the antigen has been incubated as taught in claim 26 (col. 9, lines 29-35). In a non-competitive binding process, the insoluble phase may be incubated with the reagents together in the presence of one another, as taught in claim 25 (col. 2, lines 58-62).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 13, 16, 20 and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Hevel et al (USP#4,228,237) in view of Huber et al (USP# 5,219,764).

The teachings of Hevel et al are set forth above and differ from the instant claims in not teaching the use of a homogeneous assay for the specific binding methods.

However, Huber et al teaches hapten-biotin conjugates and their use. Huber et al teaches that haptens occur in small amounts therefore detection methods are based on immunoassay that can be classified into homogeneous and heterogeneous methods. The homogeneous method has the advantage over the heterogeneous methods because there are no separation steps and therefore this assay takes less time (col.1, lines 1-34).

It would have have been obvious to one of ordinary skill in the art to use the homogeneous assay method for the detection of haptens as taught by Huber et al in the assay of Hevey et al because homogeneous assays have no separation steps and take less time thereby getting quicker assay results. With regard to claims 13 and 20, it is well known in the art to use identical haptens or their derivatives in competition assays

because they have the same or similar molecular weights or biological structure and contain the same or similar binding properties. Further, it is well within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of an obvious choice.

11. For reasons aforementioned, no claims are allowed.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. James R. Bunting (USP# 4,271,140) teaches a method and composition for double receptor specific binding assays.

B. Sheiman et al (USP#4,791,067) teaches an agglutination immunoassay for hapten involving monoclonal antibody of IGA class reagent.

C. Parsons et al (USP#5,270,166) relates to immunoassay methods for detecting and measuring the amount of an analyte in a sample by means of generic anti-hapten antibodies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
November 4, 2002

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/04/02